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IAP20 Rec'd PCT/PTO 14 FEB 2006**"INTERLAMINAR VERTEBRAL PROSTHESIS"****DESCRIPTION****Technical field**

This invention relates to an intervertebral prosthesis capable of redistributing between two adjacent vertebrae the imposed load created by degeneration of the disk located between these vertebrae without immobilizing them, but allowing them the possibility of following normal movements of the spine.

Background of the invention

Prostheses comprising a part made of deformable material are known. French Patent 2,623,085 in the name of Francis Henri Breard describes a deformable block having two opposite V-shaped ends which can be inserted between the spinous processes of two adjacent vertebrae. The block is secured there through ligatures passing through lateral inclined holes. A prosthesis according to a similar concept is described in European patent publication 0,322,334 A1, inventor Jean-Jacques Bronsard, in which one or more hollow cylindrical elastic cushions are located between the spinous processes of two adjacent vertebrae and secured there through a ligature passing through them. Other interspinous prostheses of various shapes are described in documents FR 2,717,675 and FR 2,775,183, both in the name of Jean Taylor.

All the abovementioned prostheses are located between the spinous processes and are secured there in order to at least partly absorb the load transmitted between these vertebrae. However, the centre of gravity of the spine is located behind the vertebral body, as a result of which these prostheses – being located between the spinous processes – are somewhat off centre in relation to the centre of gravity. This has the consequence that only a smaller part of that load is in fact taken up by the prosthesis. Furthermore, since for the same reason bending movements of the spine tend to cause the spinous processes to move apart or come together by a relatively large amount, these prostheses can have a tendency to tilt, with the lower part slipping backwards, and therefore losing

effectiveness.

Objects and summary of the invention

The object of the invention is to provide an intervertebral prosthesis which reduces or overcomes at least some of the disadvantages and drawbacks of the known intervertebral prostheses discussed above.

According to the invention, an intervertebral prosthesis is provided, which includes an elastic body suitable for insertion between two adjacent vertebrae alongside the laminar arch of each vertebra, and means for securing the elastic body to said laminar arches.

In this way the distance between the axis of said elastic body and the centre of gravity of the vertebral bodies is substantially reduced in comparison with the known situations described above. The advantages of locating a damping system which acts interlaminarily are undoubtedly, as it is unanimously recognized that in degenerative disease of the disk the fulcrum of the functional unit is gradually displaced towards the rear and specifically falls in the interlaminar zone behind the joint surfaces of the vertebrae.

In a preferred embodiment said securing means comprise a plate at each end of the elastic body for anchoring to the laminar arch. Said plates are preferably substantially rigid, preferably more rigid than said elastic body. Each plate has means for connection to the respective vertebra.

In a particularly advantageous embodiment of the invention, said means may include, for each plate, three projections which when the plate is fitted in position face towards the corresponding laminar arch, and in particular: a median projection of a thin shape which can be inserted into the spinal foramen of the vertebra without compressing the spinal cord, and two projections spaced apart laterally for insertion into contact with the posterior surfaces of the laminae forming the laminar arch. The assembly of the plates and the elastic body is held together through at least one ligature passing through holes made in the plates and in the elastic body, holes which, when the assembly is fitted, are in line with each other.

A prosthesis of this kind is especially suitable for the lumbar vertebrae,

from L1 to L5, and also between L5 and S1. Because the laminar arch of the vertebrae has a flattened transverse section which is inclined with respect to the axis of the spine, the shapes of the plates generally differ from each other, and can vary according to the pair of vertebrae between L1 and S1 involved.

The elastic body inserted between the plates is of a material which is flexible in all directions, so as to adjust to complex relative movements of the vertebrae. The ligature used to connect the end plates with the elastic body also preferably has some elasticity, and can be provided already attached to a right bevelled needle which is caused to pass through the holes in the plates and the elastic body and secured by rivets once tensioned. The surplus ligature is then cut off and removed.

Preferably, each of said anchoring plates has a groove on the surface in contact with the elastic body into which a tip of divaricator forceps can be inserted in order to move them apart. The technique of fitting the prosthesis according to the invention provides for positioning each plate on the laminar arch of the corresponding vertebra. Then fitting the tips of the divaricator forceps into the grooves in the plates, while these are held in position through the tips of the forceps, the vertebrae are drawn apart placing tension on the ligatures, making it possible for the elastic body to be inserted between the plates, especially from the side, and for the assembly to be subsequently ligated. The technique in fact provides for mono- and/or bilateral access to the intervertebral space and safeguards the supraspinous ligament, with minimum detachment of the ligamentum flavum in the so-called "safety zone" for insertion of the end plates.

Further advantageous embodiments and possible additional features of the prosthesis according to the invention are set forth in the attached claims.

Brief description of the drawings

The invention will be better understood from the following description and appended drawing which illustrates a non-restrictive embodiment of the invention. In the drawing:

Figures 1 and 2 show views of the assembled prosthesis in elevation, from the side and rear respectively,

Figure 3 shows a side view of the prosthesis fitted in position and in cross-section along the sagittal plane,

Figure 4 shows a rear view along IV-IV in Figure 3,

Figures 5 and 6 show cross-sectional views in plan along V-V and from beneath along VI-VI in Figure 3 respectively,

Figure 7 shows a perspective view of a component of the prosthesis in Figure 1;

Figure 8 shows a perspective view of the prosthesis during a stage of application using divaricator forceps;

Figure 9 shows a lateral view of a further embodiment of the prosthesis according to the invention;

Figures 10 and 11 show end views according to line X-X and XI-XI of Fig.9; and

Figure 12 shows a lateral view of the prosthesis of Figures 9-11 fitted on the spine

Detailed description of preferred embodiments

With reference to Figures 1, 2 and 3, a prosthesis according to the invention which has to be inserted between a pair of lumbar vertebrae, for example L2, L3, comprises an elastic body 1 of broadly cylindrical shape located between two end plates 3, 5 each of which can be anchored to the laminar arch of a corresponding vertebra and each of which has a straight groove 3S, 5S on the surface in contact with body 1 orientated at right angles to the sagittal plane along the line X-X (Figure 2). Once fitted the various parts of the prosthesis are stably secured together through two lengths of ligament 7, 9 each of which is caused to pass through corresponding holes 3D, 5D; 3E, 5E; 1D, 1E in plates 3, 5 and elastic body 1 respectively, by means of a straight needle which is not shown, and is secured after being tensioned through rivets 11 fitted to the outer surfaces of plates 3, 5.

Body 1 is made of elastic material which is flexible in all directions and

may be coated with flexible material (e.g. polyester, etc.) suitable for remaining in contact with human tissues without damaging them or giving rise to rejection reactions.

With reference to Figures 1, 2, 3, 4 and 5, upper plate 3 has on its upper surface a central tooth 3A located on the side of the perimeter of the plate facing the spinal foramen CM and a pair of lateral teeth 3B, 3C located symmetrically on opposite sides of the sagittal plane along line X-X, these teeth facing upwards and being slightly inclined with their upper ends towards the left (looking at Figure 3). Having this shape, this plate is dimensioned so that it can be inserted from beneath against the laminar arch A2 (Figure 5) of upper vertebra L2 with central tooth 3A located between the inner central part of laminar arch A2 and spinal foramen CM, and lateral teeth 3B, 3C each in contact with a lateral outer surface (FB, FC) of the corresponding lamina forming said laminar arch A2.

With reference to Figures 1, 2, 3, 4 and 6, lower plate 5 has on its lower surface a central tooth 5A located on the side of the perimeter of the plate facing the spinal foramen CM and a pair of lateral teeth 5B, 5C located symmetrically on opposite sides of the sagittal plane along the line X-X (Figure 5), these teeth facing downwards and being slightly inclined with their lower ends towards the right (looking at Figure 3). Having this shape plate 5 is dimensioned in such a way that it can be inserted downwards against the laminar arch A3 (Figure 6) of lower vertebra L3, with central tooth 5A located between the inner central part of laminar arch A3 and the spinal foramen CM, and lateral teeth 5B, 5C each in contact with a lateral outer surface GB, GC of the corresponding lamina forming said laminar arch A3.

Once plates 3, 5 have been fitted to corresponding vertebrae L2, L3, the terminal tips P3, P5 (Figure 8) of divaricator forceps P are inserted into grooves 3S, 5S and plates 3, 5 together with vertebrae L2, L3 to which they are fitted are moved apart as far as possible. During this stage the divaricator forceps also have the function of holding the plates in position. Thus elastic body 1 can be inserted laterally between plates 3, 5 without

- having to interrupt the supraspinál ligament, and then ligaments 7, 9 can be passed through appropriate holes 3D, 3E; 5D, 5E in plates 3, 5 and 1D, 1E of body 1 and fixed thereto through rivets 11.

Because the dimensions of the vertebrae vary from one individual to another, and for one individual from one vertebra to another along the length of the spine, these plates are manufactured in various sizes so as to cover a wide range of possibilities of use.

Figures 9-12 show a second embodiment of prosthesis according to the invention. The same reference numbers are used to designate the same or equivalent parts or elements of the prosthesis.

The elastic body 1 has a slightly different shape and is not cylindrical but rather has planar lateral surfaces. Such shape can be used also in the embodiment of the previous figures. The projections 3A, 3B, 3C and 5A, 5B and 5C are shown in a different shape and dimension by way of example. The shape of these portions of the prosthesis can depend upon the location where it has to be applied and/or the morphological characteristics of the patient which has to receive the prosthesis.

The main difference of the prosthesis of Figures 9-12 with respect to the previously described embodiment consists in the presence of an auxiliary ligament 21 which is used to connect the two spinous processes SP1 and SP2 of the adjacent vertebrae designated L in Figure 12, between which the prosthesis is inserted. The ligament 21 embraces the two spinous processes SP1, SP2 and provides an augmentation to the superspinous ligament and a replacement for the interspinous ligament, said auxiliary ligament 21 extending along the same inclined development of the interspinous ligament, i.e. from the apex of the upper spinous process to the base of the lower spinous process.

The ligament 21 is anchored to the two plates 3, 5 by means of suitable connection or anchoring devices. In the example shown in Figures 9-12, each plate 3, 5 is provided with a pair of opposite hooks designated 3H and 5H respectively, on both sides of the plates. The hooks 3H and 5H are oppositely oriented: the hooks 3H are opened backwards, i.e. opposite the

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spinal foramén, while the hooks 5H are opened towards said spinal foramen.

It will be understood that the drawing only shows an example provided as a practical embodiment of the invention, and the invention may vary in shape and arrangement without thereby going beyond the scope of the concept underlying the invention itself. Any reference numbers included in the appended claims are purely to assist a reading of the claims with reference to the description, and do not restrict the scope of the protection represented by the claims.